

total of 44 states were valued in TTO (all MVH states except 'unconscious', adding extra two more 23333 and 32,333). States were divided into two fixed blocks of 23 with 22,222 and 33,333 in both sets. Modeling was performed using GRETl and WinBugs software. **RESULTS:** Since February till May 2008, 321 interviews were collected. Modeling on 7245 valuations resulted in additive model with N3 and I3 factors, all coefficients statistically significant, R^2 equal to 0.37 and value -0.647 for 33,333 health state. **CONCLUSIONS:** This is the first EQ-5D value set available for Central and Eastern Europe so far. Our study proved that valuation tasks can be performed at reasonable costs.

PM32

METHODS FOR ADDRESSING USE OF PRO INSTRUMENTS IN THE SAME LANGUAGE FOR DIFFERENT COUNTRIES: BEST PRACTICE GUIDELINES FOR DECISION-MAKING AND TRANSLATION OR ADAPTATION

Eremenco S¹, Houchin C², Gawlicki M³, Chong LY⁴

¹United BioSource Corporation, Bethesda, MD, USA, ²Oxford Outcomes Ltd, Oxford, Oxon, UK, ³Corporate Translations, Inc, East Hartford, CT, USA, ⁴NCC-AC, Royal College of Surgeons, London, UK

OBJECTIVES: The 2005 report of the ISPOR Task Force that studied Translation and Cultural Adaptation left several questions unanswered. Recently the Task Force completed a new report in which it explored topics not addressed in its previous work. Among the topics studied was the issue of how to approach the creation of a PRO instrument when the same language is required for use in different countries. The objective of this investigation was to develop a method for determining which of these suggested approaches is best suited to any particular situation by looking at key aspects of the questionnaire and the languages involved, and, once the approach is identified, to describe in detail the methods for carrying out the selected approach. **METHODS:** A literature review was conducted to investigate existing guidelines and approaches used to address the same language in different countries. **RESULTS:** Based on the literature review and our practical experience, three primary approaches were identified and investigated: country-specific translation, same language adaptation, and universal translation, as well as many combinations of all three approaches. This new research developed a decision making tool and scenarios illustrating the process for choosing and then translating or adapting an instrument using each of the three methods. **CONCLUSIONS:** The Task Force developed recommendations for choosing a suitable approach for commonly encountered situations in the form of a decision-tree flowchart as well as best practice guidelines for how to carry out each of the three suggested approaches.

PM33

THE ROLE OF RANKING DATA IN HEALTH VALUATION

Chuang LH, Kind P, Zarate V, Weatherly H

University of York, York, UK

OBJECTIVES: The use of ordinal preferences based on the rank order of health states has recently attracted attention. A ranking task has traditionally had a limited role as a warm-up exercise prior to more complex preference elicitation methods such as Time Trade-Off. This paper reports on the use of rank data as the primary source of preferences in a health valuation study. **METHODS:** 205 university students ranked and rated (using a VAS scale) a subset of 14 EQ-5D health states selected from the US Valuation Survey. The order of presentation was

randomised. The logical consistency and number of tied health states were computed for each method. The agreement amongst participants was measured by Kendall's Coefficient of Concordance (W). Consistency on a within-participant basis was measured by counting the number of states having the same rank as determined for each method. Scale values estimated from the rank data using a conditional logistic regression model were compared with results obtained from a random effects model applied to the VAS ratings. **RESULTS:** Seventy-six percent of participants made no logically inconsistent responses in ranking health states. This figure is higher than corresponding 62% recorded for the VAS ratings. An average of 2 states were tied in the ranking task; this figure rose threefold for the VAS rating. Kendall's W for the ranking task was higher than that for VAS rating. An average of 4/14 states per participant were ranked identically in the two preference elicitation methods. Coefficients based on the rank data yielded results that were similar to those obtained from the VAS data. **CONCLUSIONS:** Ranking produces data that are logically superior to those obtained from VAS rating. Standard modelling methods enable the recovery of an interval scale for EQ-5D health states. The use of ordinal rank data in deriving health value should be encouraged.

PM34

METHODOLOGIES FOR ASSESSING AND DEMONSTRATING DATA SATURATION IN QUALITATIVE INQUIRY SUPPORTING PATIENT-REPORTED OUTCOMES RESEARCH

Nixon A, Wild D

Oxford Outcomes Ltd, Oxford, UK

OBJECTIVES: The role of qualitative research is patient-reported outcomes (PRO) research is pivotal. Theoretical saturation is the gold standard for determining research sample sizes in qualitative research. There are currently no practical guidelines for estimating sample sizes in qualitative PRO research to a sufficient standard for regulatory review. This paper provides an evidence-based foundation for the evaluation of theoretical saturation by operationalising the concept of theoretical saturation with a specific focus on qualitative inquiry for the purpose of PRO research. **METHODS:** Data from five PRO studies were prospectively analysed following a three-step process: 1) develop a codebook; 2) document progression of theme identification, and 3) evaluate theoretical saturation. Selected studies represent a typical range of qualitative PRO studies: development of conceptual models, development of PROs, PRO measure content validity evaluation and health state development. All studies involved thematic analysis. Data were systematically documented to evaluate the degree of theoretical saturation and variability of the course of the thematic analysis. This study presents a collated secondary analysis of the theoretical saturation data from these five studies. **RESULTS:** Despite the variability in the nature of the PRO studies, disease areas, study design etc., there is a clearly consistent story emerging from these data. In each interview 95% of the thematic discovery occurred within the first 10 interviews/focus groups in nearly all instances, with relatively theoretically insubstantive codes being introduced beyond the point of 10 interviews. **CONCLUSIONS:** Theoretical saturation is an essential component of assessing qualitative data for validity. Failure to achieve theoretical saturation will affect the content validity of the PRO measure resulting poor PRO measurement tools. As demonstrated in this study PRO qualitative research is generally focused on a homogenous patient population, therefore theoretical saturation is regularly achieved within 10 focus groups or individual interviews.